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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,416	04/30/2001	Xiao Xiao	DE1253	4144

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/845,416	XIAO, XIAO	
Examiner	Art Unit	
Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-13, 16, 17, 24-28 is/are allowed.
- 6) ☒ Claim(s) 1-5, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 1-17 and 24-28 are pending.

Applicant's traversal and the amendment to claims 1-13 in paper filed on 8/24/04 is acknowledged and considered.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 written description for claims 1-5 and 14-15 of this application.

The provisional application 60/200,777 filed on 4/28/00 does not disclose 4 rod repeat mini-dystrophins.

Instant claims 1-5 and 14-15: Provisional Application '777 does not provide written support for these claims.

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The lack of teaching in the provisional application is highlighted by page 56 and 60.

“To ensure sufficient physical flexibility of the protein, all of our mini-dystrophins still retain at least five rod repeats (R1, R2, R22, R23 & R24) and 2 hinges (H1 and H4) in the central rod domain (Fig. 1).” See page 56.

“However, the mini-dystrophin genes reported here accommodated at least 5 rod repeats (R1, R2, R22, R23 and R24) and two hinges (H1 and H4). Therefore we hypothesized that the length of the central rod domain is the most critical factor, based on the fact that a major role of dystrophin is to crosslink the myofiber cytoskeleton and plasma membrane and stabilize the structure during muscle contraction. If the dystrophin is too short to span the sliding distance between the cytoskeleton and plasma membrane during muscle contraction, the crosslink will be disrupted and the muscle membrane will become unstable and prone to mechanical damages.” See page 60.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 4, 5, 14, and 15 remain rejected under 35 U.S.C. 102(e) as being anticipated by Chamberlain et al. (US 2003/0216332). Chamberlain teaches a mini-dystrophin

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nucleic acid encoding a protein consisting of N-terminal domain, four spectrin-like repeats (rod repeats), an H1 and H4 domain of the dystrophin gene, a cysteine-rich domain and a C-terminal domain (page 8 and Figure 27). Chamberlain teaches that the nucleic acid is less than 5 kb in length (page 4). Chamberlain teaches that the protein can further comprise an H2 domain or an H3 domain of the dystrophin gene (Figure 27). Chamberlain further teaches using AAV vectors (pages 40-41). Chamberlain further teaches linking the nucleic acid to expression control elements (e.g., MCK or CMV) in an AAV vector (page 7 and pages 36-38).

Applicant's arguments filed 8/24/04 have been fully considered but they are not persuasive because priority to US provisional application 60/200,777 filed on 4/28/00 has not been granted in view of application '777 not providing written support under 112 first paragraph for a mini-dystrophin gene having 4 rod repeats as recited in claims 1-5 and 14-15.

The Declaration by Dr. Xiao filed on 8/24/04 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(e) reference.

Pages 6 and 56 of '777 cited by Dr. Xiao in the Declaration (see pages 2-3) do not provide written support for an isolated nucleotide sequence comprising a mini-gene encoding a protein having four rod repeats. On page 6, the applicant states that the present invention provides a mini-dystrophin gene with 1/3 of the full-length dystrophin coding sequence. However, other than support for a mini-dystrophin consisting of 5 or 6 rod repeats, there is nothing in the specification that would lead one skilled in the art to a mini-dystrophin encoding an amino acid sequence consisting of four rod repeats.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate

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as to modifications that the inventor might have envisioned, but failed to disclose.”

Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

On page 56, the applicant asserts that the statement “deleting $\frac{3}{4}$ of the central rod domain” provides support for the claims because when $\frac{3}{4}$ is converted into a decimal fraction of relevant significant digit (0.8), yields a domain deletion portion = $0.8 \times 24 = 19.2$ rods, which in turn due to the whole number character of repeat units require deletions of 20 of the 24 naturally occurring rods to produce a 4 rod construct. However, the statement on page 56 of ‘777 clearly indicates that only 19 rods were deleted and not 20 rods as asserted by applicant’s calculation. In addition, a skilled artisan would not calculate $\frac{3}{4}$ of 24 using applicant’s calculation because $\frac{3}{4}$ of 24 is 18.

Furthermore, the grant application (Exhibit 1) cited by Dr. Xiao for support of the claims does not disclose a mini-dystrophin gene encoding an amino acid sequence consisting of 4 rod repeats. In addition, the abstract (Exhibit 2) and journal article (Exhibit 3) were published after the filing date of the provisional application and do not disclose a mini-dystrophin encoding an amino acid sequence consisting of 4 rod repeats.

Conclusion

Claims 6-13, 16, 17, and 24-28 are in condition for allowance because the claims are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

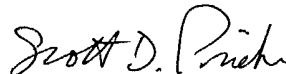
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER